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Interventional bleeding, hematoma and scar-formation after vacuum-biopsy under stereotactic guidance: Mammotome®-system 11g/8g vs. ATEC®-system 12g/9g

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ABSTRACT

Purpose: To evaluate prospectively the correlation of scar-formations after vacuum-assisted biopsy with different systems and needle-sizes and interventional bleeding/post-interventional hematoma.
Methods and materials: Between 01/2008 and 12/2009, 479 patients underwent vacuum-assisted biopsy under stereotactic-guidance, using the Mammotome®-system with 11/8-gauge and ATEC®-system with 12/9-gauge, whereas in 178 cases with representative benign histology no surgical-biopsy after vacuum-assisted biopsy was performed and at least a 2-plane-follow-up-mammogram after 6 month post-vacuum-assisted biopsy was available. Bleeding during intervention, hematoma post-intervention and scar-tissue was scored as minimal and moderate/severe. Statistical analysis included Chi-Square-trend-test, p-value <0.05 was considered to be significant.
Results: Significantly more bleedings and post-interventional hematomas for 8-gauge-Mammotome®-system vs. 11-gauge-Mammotome®-system (41.9% vs. 8.4%, $p < 0.001$/35.5% vs. 16.7%, $p = 0.029$), no significant-differences for the ATEC®-systems 9-gauge vs. 12-gauge (26.9% vs. 29.7%, $p = 0.799$/42.3% vs. 43.2%, $p = 0.596$). 11-gauge-Mammotome®-system vs. ATEC®-12-gauge-system revealed significantly less bleedings/hematomas (8.4% vs. 29.7%, $p = 0.015$/16.7% vs. 43.2%, $p = 0.001$), no significant differences for the large-systems ($p = 0.135$/$p = 0.352$). Follow-up of Mammotome®-11/8-gauge-system system has shown 13.1/16.1% minimal scar-formation and 1.2/3.2% moderate/severe scars, whereas ATEC®-12/9-gauge-system has shown 10.8/3.8% minimal scar-formation and 0/11.5% moderate/severe scars, no significant differences. No significant difference was found when comparing Mammotome®-11/8-g-systems vs. ATEC®-12/9-g-systems ($p = 0.609$/$p = 0.823$). There was also no correlation between risk of scar-formation after occurrence of bleeding or hematoma with any examined VAB-system or any needle size in this study ($p = 0.800$).
Conclusion: Using larger needle-sizes significantly (Mammotome®)/not significant for ATEC®) more interventional bleedings and post-interventional hematomas were detected, only a tendency concerning scar-formation.

1. Introduction

In the last decade stereotactic breast biopsy has rapidly gained acceptance as the technique of choice for preoperative histopathologic diagnosis for non-palpable mammographic breast lesions that are not visible on ultrasound. The effectiveness and high accuracy of non-operative diagnosis achieved by this technique has led to reduced numbers of open surgical biopsies [1]. Stereotactically guided vacuum assisted-biopsy (VAB) includes devices ranging from 7- to 14-gauge. Vacuum-biopsy is more accurate than core-needle biopsy in the evaluation of microcalcifications, and a metaanalysis has proved the value of VAB for the diagnosis of breast cancer to be good. VAB provides lower mis- and underestimation rates than core biopsy does [2–4]. However, concerning complication rates for bleeding or hematoma using different VAB systems, data available in the literature is limited. There are only a

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few studies showing various results concerning suspicious changes, scar formation or abnormalities on follow-up mammograms after vacuum-biopsy [5,6]. This may cause problems in the diagnosis of potential malignancy in the breast.

The purpose of our prospective study was to evaluate the performance of different VAB-systems and needle-sizes in VAB in terms of the periinterventional complications bleeding and hematoma and in terms of postinterventional scar formations. The VAB systems of interest were Mammotome® (Ethicon Endosurgery, Cincinatti, USA) implementing 11- and 8-gauge needles and ATEC®-VAB system (Suros, Indianapolis, USA) implementing 12- and 9-gauge needles.

2. Methods

Between January 2008 and December 2009, 479 patients underwent consecutively VAB under stereotactic guidance, using the Mammotome® system with 11- and 8-gauge needles or the ATEC® system with 12- and 9-gauge needles. Both systems are technically different. Different to the Mammotome® system the ATEC® system has a collecting vessel for the harvested biopsy samples and a lavage function to flush the biopsy cavity with NaCl solution 0.9%.

All biopsies were performed on a digital prone table (Fischer Imaging, Denver, CO, USA), and all patients signed written informed consent. The study was conducted according the current revision of the Declaration of Helsinki for Good Clinical Practice. 280 patients (58.5%) had benign histologic findings, of which 178 with representative histology did not undergo open surgical biopsy post VAB and simultaneously provided at least a 2-plane follow-up mammogram after 6 month post VAB. Among these 178 patients, 155 presented with microcalcifications, 11 with masses and 7 seven with architectural distortions. 5 patients had masses with associated microcalcifications. The mean age was 52 years (range, 32–81 years). For lesions 15 mm or greater in diameter an 8- or 9-gauge VAB system was used, for lesions smaller than 15 mm in diameter an 11- or 12-gauge VAB-system was used. In each case 24 biopsy cylinders should be taken according to the guidelines. All procedures were carried out by physicians with an experience of more than 500 VAB procedures each.

Both VAB systems suck breast tissue into a biopsy needle, and a rotating knife cuts off tissue samples. Aspirated by a vacuum stream, the tissue samples are transported to the adverse needle end to be removed there. As mentioned before, the systems are technically different. The ATEC® system is equipped with a collecting vessel for the harvested tissue and with a lavage function to flush the biopsy cavity with NaCl solution 0.9%. Storing the harvested tissue samples automatically in the provided collecting vessel, the ATEC®-VAB system has to be emptied after twelve biopsy runs. Using the Mammotome® system a technician has to remove each single sample from the needle with forceps.

Local anesthesia was administered with 20 ml prilocaine with adrenaline (epinephrine) 1:200.000. After calculating the exact localization of the suspect lesion the needle was advanced to the target lesion. The needle position was checked by pre- and post-biopsy views in plus 15° and minus 15° projection. Then, the tissue was extracted. Finally, post procedure control was conducted by documenting the biopsy cavity in two projection planes. The wound was manually compressed for 10 min, and sealed with sterile strips and a compression bandage. A postinterventional mammogram in craniocaudal and mediolateral projection planes was obtained in each case 45 min post biopsy.

A case record included patient identification, lesion type, access path for biopsy, needle size and type, number of samples, clip deployment, potential complications (bleeding, hematoma, pain) and number of planes in the mammographic follow-up. Bleeding during intervention, hematoma post intervention and scar tissue formation was scored small, moderate and severe. Small bleeding/hematoma was defined as a maximum of 20 ml blood aspirated/discrete density area of a maximum extension of 1.5 cm × 1.5 cm × 1.5 cm in projection of the target area in postinterventional mammography. Moderate bleeding/hematoma was defined as a maximum of 20–40 ml blood aspirated/density area of a maximum of 3.0 cm × 3.0 cm × 3.0 cm, whereas a severe bleeding/hematoma was classified by more than 40 ml blood aspirated/density area of more than 3.0 cm × 3.0 cm × 3.0 cm. The definitions for scar formation were for minimal a very vague density seen only along the *z*-axis of the biopsy probe, for moderate a density area or an architectural distortion on one or both projection planes in the target area of the biopsy site, and for severe a lesion causing diagnostic problems regardless of the knowledge of previous biopsies and thus necessitating additional mammography, ultrasound, re-biopsy or magnetic resonance imaging. The protocol for all follow-up mammograms included at least craniocaudal and mediolateral oblique projection planes.

SPSS 15 (SPSS, Chicago) was used for statistical analysis. For inter- and intra-group analysis, differences between the groups were analyzed using Chi-Square trend test. A p-value of <0.05 was considered to be significant.

3. Results

Mammotome® 11-gauge and 8-gauge needles were used in 84 and 31 cases, respectively. ATEC® 12-gauge and 9-gauge needles were used in 37 and 26 cases, respectively. In 38 biopsies a craniocaudal approach was chosen (21.3%), in 108 cases a lateromedial approach (60.7%), and in 32 cases a mediolateral approach (18.0%). The mean number of biopsy samples taken was $n = 22.71$ for the Mammotome® 8-gauge needle (range, 6–24; standard deviation (SD), 4.173), $n = 24.48$ for the Mammotome® 11-gauge needle (range, 7–48; SD, 3.695), $n = 24.46$ for the ATEC® 9-gauge needle (range, 24-36; SD, 2.353), and $n = 24.65$ for the ATEC® 12-gauge needle (range, 12–35; SD, 3.946). A clip was deployed in 48% of all cases. All specimen radiographs revealed the suspect lesions, and histology was representative in all cases. For all 178 patients, at least a 6 month follow-up was available. In 53% an additional 12–24 month follow-up was available, which has not shown any changes concerning development of scar formations in any case.

3.1. Bleeding while VAB

A small bleeding was observed in 5/84 (6.0%) cases in VAB with the Mammotome® 11-gauge needle, and in 9/31 (29.0%) cases using the Mammotome® 8-gauge needle (Fig. 1). Moderate/severe bleeding was detected in two (2.4%) cases using the Mammotome® 11-gauge needle, and in four (12.9%) cases using the Mammotome® 8-gauge needle, respectively. Comparing the bleeding rates for the Mammotome® 8-gauge system vs. the Mammotome® 11-gauge system, the difference reached level of significance ($p < 0.001$). VAB was aborted in one case after twelve biopsy runs with the Mammotome® 11-gauge needle due to pain during the procedure, and in three cases after 18/12/10 biopsy runs, respectively, with the Mammotome® 8-gauge needle due to moderate to severe bleeding.

A small bleeding was observed in 10/37 (27.0%) cases performing the VAB with the ATEC® 12-gauge needle, and in 7/26 (26.9%) cases using the ATEC® 9-gauge device (Fig. 1). The results did not show significant differences between the different needle sizes of the two ATEC® devices ($p = 0.799$). Moderate/severe bleeding was detected in one (2.7%) case using the ATEC® 12-gauge needle, and VAB was stopped after twelve biopsy runs. There was no moderate/severe bleeding in VAB with the ATEC® 9-gauge needle.

Table 1
Comparison of bleeding rates using different needle sizes: 8-g- vs. 9-g- and 11-g- vs. 12-g-VAB-systems.

Needle size			Biopsy system		Total
			Mammotome®	ATEC®	
Large (8g/9g)	Bleeding	None	18 (58.1%)	19 (73.1%)	37 (64.9%)
		Small	9 (29.0%)	7 (26.9%)	16 (28.1%)
[a] $p = 0.135$		Moderate/severe	4 (12.9%)	0 (0.0%)	4 (7.0%)
	Total		31 (100.0%)	26 (100.0%)	57 (100.0%)
Small (11g/12g)	Bleeding	None	77 (91.7%)	26 (70.3%)	103 (85.1%)
		Small	5 (6.0%)	10 (27.0%)	15 (12.4%)
[a] $p = 0.015$		Moderate/severe	2 (2.4%)	1 (2.7%)	3 (2.5%)
	Total		84 (100.0%)	37 (100.0%)	121 (100.0%)

[a] Chi-square trend test.

In the inter-group analysis comparing the bleeding rates of the Mammotome® 8-gauge needle vs. the ATEC® 9-gauge needle, there were no significant differences ($p = 0.135$) (Table 1).

In the inter-group analysis comparing the bleeding rates of the Mammotome® 11-gauge needle vs. the ATEC® 12-gauge needle, there were significantly less bleedings in favor of the Mammotome® 11-gauge needle ($p = 0.015$) (Table 1).

3.2. Post-interventional hematoma

A small hematoma was observed in 13/84 (15.5%) cases after performing VAB with the Mammotome® 11-gauge needle, and in 9/31 (29.0%) cases with the Mammotome® 8-gauge needle (Fig. 2). A moderate/severe hematoma was detected in one (1.2%) case in the postinterventional mammogram after VAB with the Mammotome® 11-gauge needle, and in two (6.5%) cases after VAB with the Mammotome® 8-gauge needle, respectively. Hematoma occurred significantly more often using the 8-gauge Mammotome® needle if compared to the 11-gauge Mammotome® needle ($p = 0.029$).

In 13/37 (35.1%) cases a small hematoma occurred after VAB with the ATEC® 12-gauge needle, and in 6/26 (23.1%) cases using the ATEC® 9-gauge needle (Fig. 2). In 3/37 (8.1%) cases a moderate/severe hematoma was detected in the postinterventional mammogram after VAB with ATEC® 12-gauge needle, and in 5/26 (19.2%) cases with ATEC® 9-gauge needle, respectively. There were no significant differences between the different needle sizes in the ATEC® system group ($p = 0.596$).

In the inter-group analysis of postinterventional hematoma rates of the Mammotome® 8-gauge system vs. the ATEC® 9-gauge system, there were no significant differences ($p = 0.352$) (Table 2).

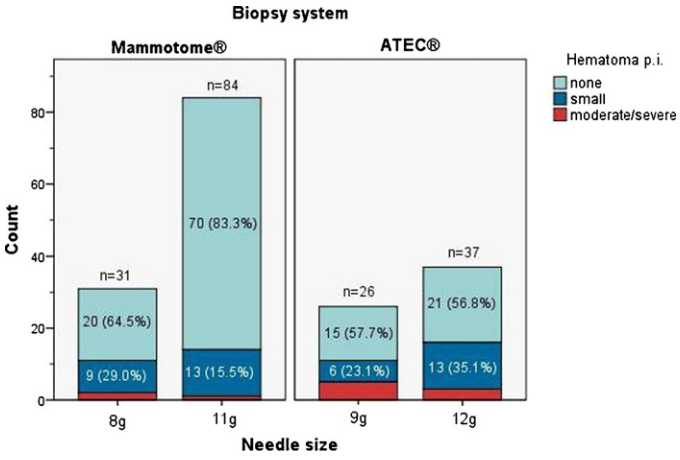

Fig. 2. Comparison of postinterventional hematoma-rates using different needle sizes: 8-g- vs. 11-g- and 9-g- vs. 12-g-VAB-systems.

The inter-group analysis of the Mammotome® 11-gauge system vs. the ATEC® 12-gauge system revealed significantly less hematomas ($p = 0.001$) (Table 2).

3.3. Scar formation after VAB

Small scar formation was observed in 11/84 (13.1%) cases after VAB with the Mammotome® 11-gauge needle, and in 5/31 (16.1%) cases using the Mammotome® 8-gauge needle (Table 3 and Fig. 3). In one (1.2%) case each a moderate/severe scar was detected in the follow-up mammogram after VAB with the Mammotome®

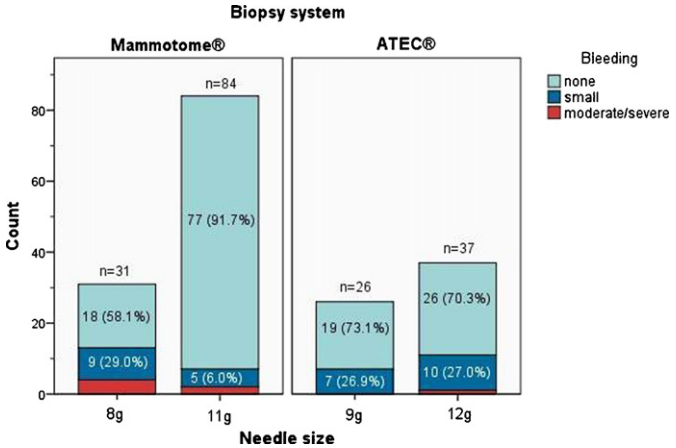

Fig. 1. Comparison of bleeding rates while intervention using different needle sizes: 8-g- vs 11-g- and 9-g- vs. 12-g-VAB-systems.

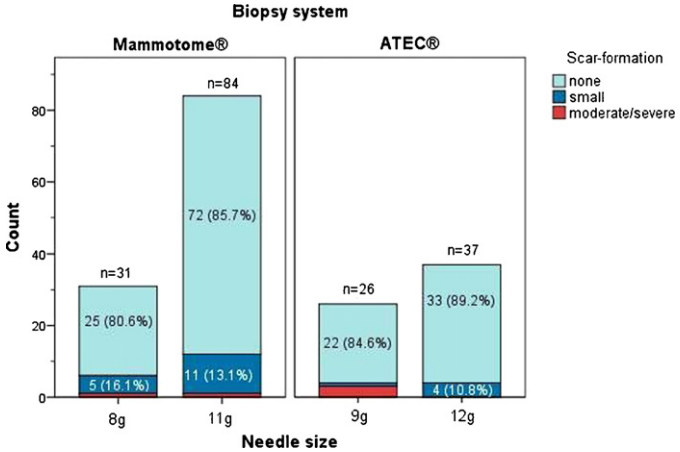

Fig. 3. Comparison of scar-formation rates using different needle sizes: 8-g- vs. 11-g- and 9-g- vs. 12-g-VAB-systems.

Table 2
Comparison of post-interventional hematoma-rates using different needle sizes: 8-g- vs. 9-g- and 11-g- vs. 12-g-VAB-systems.

Needle size			Biopsy system		Total
			Mammotome®	ATEC®	
Large (8g/9g)	Hematoma p.i.	None	20 (64.5%)	15 (57.7%)	35 (61.4%)
		Small	9 (29.0%)	6 (23.1%)	15 (26.3%)
[a] $p = 0.352$		Moderate/severe	2 (6.5%)	5 (19.2%)	7 (12.3%)
	Total		31 (100.0%)	26 (100.0%)	57 (100.0%)
Small (11g/12g)	Hematoma p.i.	None	70 (83.3%)	21 (56.8%)	91 (75.2%)
		Small	13 (15.5%)	13 (35.1%)	26 (21.5%)
[a] $p = 0.001$		Moderate/severe	1 (1.2%)	3 (8.1%)	4 (3.3%)
	Total		84 (100.0%)	37 (100.0%)	121 (100.0%)

[a] Chi-square trend test.

11-gauge needle and with the Mammotome® 8-gauge needle, respectively.

In 4/37 (10.8%) cases small scar formation could be detected after VAB with the ATEC® 12-gauge needle, and in 1/26 (3.8%) cases using the ATEC® 9-gauge needle (Table 3 and Fig. 3). There was no moderate/severe scar formation in the follow-up mammogram after VAB with ATEC® 12-gauge needle, but there were 3/26 (11.5%) cases of moderate/severe scar formation after VAB with the ATEC® 9-gauge needle.

In the intra-group analysis, the results did not show significant differences concerning occurrence of scar formation between the different needle sizes in the Mammotome® system group ($p = 0.461$) and in the ATEC® system group ($p = 0.308$), respectively (Table 3).

In the inter-group analysis comparing the Mammotome® 8-gauge system vs. the ATEC® 9-gauge system in terms of scar formation, there were no significant differences ($p = 0.823$) (Table 4). Neither were there any significant differences in the comparison of the Mammotome® 11-gauge system vs. the ATEC® 12-gauge system ($p = 0.609$).

There was no correlation between risk of scar formation and occurrence of bleeding or hematoma with any examined VAB system or any needle size in this study ($p = 0.800$).

4. Discussion

Scar formation after open surgical breast biopsy for benign or malignant lesions is well known and described in the literature [7,8]. Mammographic findings also include architectural distortions with or without concomitant mass, micro- or macrocalcifications, opaque foreign body, asymmetric tissue defect, oil cysts, skin thickening or deformity. Especially scar formation may mimic direct mammographic signs of malignancy. But those findings usually present stable or regressive on follow-up radiological examinations [7]. It is essential that the radiologist knows the patient's history and the location of prior surgery exactly to prevent further examinations or interventional procedures from the patient.

In case of suspicious mammographic findings image-guided breast biopsy is widely used, especially in the evaluation of non-palpable breast lesions. VAB enables more accurate and larger volume tissue sampling than plain core-needle biopsy. The standard size of needles is usually 10-, 11- or 12-gauge, whereas 8- or 9-gauge needles are used for larger lesions and therapeutic excisions. The VAB technique provides larger specimen and a higher calcification retrieval rate, is less sensitive to targeting errors and has lower underestimation rates than core-needle biopsy [9]. The vacuum may also be supportive for blood suction out of the biopsy cavity to reduce the chance of hematoma. Significant bleeding occurs in 1–3.9%, and the hematoma rate increases with cumulative aspiration of blood during the biopsy procedure [10–12].

To the best of our knowledge, there is currently no data reported about follow-up in mammographic findings after VAB with larger needle systems of 8- or 9-gauge, and there are no results available about the ATEC® system, that has been marketed since 2007.

Scar formation after image-guided breast biopsy using a 14-gauge biopsy device has not been reported in literature. However, different results are reported for postinterventional mammographic findings after VAB with 11-gauge systems [5,6,13–15]. Jackman et al. [14] described no scar formation. Lamm et al. [5] found up to 2% scar formation post VAB that was only detectable in the mammographic projection plane parallel to the biopsy approach (z-axis), but was not detectable in the orthogonal plane. Rotter et al. [15] detected up to 3.6% of moderate scar formation in one projection plane, and they described for up to 13.5% of the cases a vague density (minimal scar/no relevant scarring). A similar rate of 14% of minimal scar formation is also reported by Kettritz et al. [13]. Though, no misinterpretation of the mammographic findings resulted. Only in four out of 2874 cases scar tissue might lead to problems, if the radiologist would not know the patient's history of VAB and corresponding approach. Yazici et al. [6] described

Table 3
Comparison of scar-formation rates using different needle sizes: 8-g- vs. 11-g- and 9-g- vs. 12-g-VAB-systems.

Biopsy system			Needle size		Total
			large	small	
Mammotome®	Scar-formation	None	25 (80.6%)	72 (85.7%)	97 (84.3%)
		Small	5 (16.1%)	11 (13.1%)	16 (13.9%)
[a] $p = 0.461$		Moderate/severe	1 (3.2%)	1 (1.2%)	2 (1.7%)
	Total		31 (100.0%)	84 (100.0%)	115 (100.0%)
ATEC®	Scar-formation	None	22 (84.6%)	33 (89.2%)	55 (87.3%)
		Small	1 (3.8%)	4 (10.8%)	5 (7.9%)
[a] $p = 0.308$		Moderate/severe	3 (11.5%)	0 (0.0%)	3 (4.8%)
	Total		26 (100.0%)	37 (100.0%)	63 (100.0%)

[a] Chi Square trend test.

Table 4
Comparison of scar-formation rates using different needle sizes: 8-g- vs. 9-g- and 11-g- vs. 12-g-VAB-systems.

Needle size			Biopsy system		Total
			Mammotome®	ATEC®	
Large (8g/9g)	Scar-formation	None	25 (80.6%)	22 (84.6%)	47 (82.5%)
		Small	5 (16.1%)	1 (3.8%)	6 (10.5%)
[a] $p = 0.823$		Moderate/severe	1 (3.2%)	3 (11.5%)	4 (7.0%)
	Total		31 (100.0%)	26 (100.0%)	57 (100.0%)
Small (11g/12g)	Scar-formation	None	72 (85.7%)	33 (89.2%)	105 (86.8%)
		Small	11 (13.1%)	4 (10.8%)	15 (12.4%)
[a] $p = 0.609$		Moderate/severe	1 (1.2%)	0 (0.0%)	1 (0.8%)
	Total		84 (100.0%)	37 (100.0%)	121 (100.0%)

[a] Chi Square trend test.

4.3% scar formations on follow-up mammograms after VAB, and they found no correlation between postinterventional hematoma and development of scar formation. In that study no correlation between number of specimen and scar tissue was observed. Our presented data for developing minimal or moderate scar formation lies for all used VAB devices and needle sizes in the same range as reported in literature.

The follow-up after VAB with a Mammotome® 11-gauge system has shown 13.1% minimal and 1.2% moderate/severe scar formation, whereas the larger Mammotome® 8-gauge system revealed slightly more minimal and moderate/severe scar formations with 16.1% and 3.2%, respectively.

The follow-up after VAB with the ATEC® 12-gauge system has shown 10.8% minimal and no moderate/severe scar formation. The larger ATEC® 9-gauge system caused minimal scar formation in 3.8% of the cases, and moderate/severe scar formation was found in 11.5% of the cases.

There is no significant difference concerning risk of scar formation when comparing the Mammotome® 11-gauge system vs. the ATEC® 12-gauge system and the Mammotome® 8-gauge system vs. the ATEC® 9-gauge system. Apparently, scar formation is more influenced by the larger biopsy cavity with an enlarged zone of injured breast tissue than by the different techniques of the rotating cutting knifes.

Applying to the two systems and all needle-sizes, an approximately cylindric tissue sample, longer than wide, is removed. In every scar formation, the density or architectural distortion appeared densest in the projection plane parallel to the biopsy needle approach, and only vague or imperceptible in the second plane. Only in case of moderate/severe scar formation a vague density appeared in the orthogonal plane (Fig. 4a pre-biopsy, Fig. 4b–e).

The bleeding rate ($p < 0.001$) and the postinterventional hematoma rate ($p = 0.029$) was significantly higher for the Mammotome® 8-gauge vs. the Mammotome® 11-gauge system, which can be explained by a larger biopsy cavity with a greater area of injured breast tissue caused by the rotating cutting knife. Among the ATEC® systems with 12-gauge vs. 9-gauge no significant differences were found for the bleeding rate ($p = 0.799$) and the postinterventional hematoma rate ($p = 0.596$). Thus, the similar bleeding rates of the two needle sizes are obviously more influenced by the technique of the rotating cutting knife in the ATEC® systems causing more tissue fragmentation than by the biopsy cavity size. In another study concerning histologic quality we found significantly better quality for specimen harvested with the Mammotome® system than harvested with the ATEC® system (study completed, results not yet published). Additionally, using the ATEC® system significantly more tissue fragmentations and crush artefacts were observed in the specimen. Thus, corresponding to the tissue fragmentations and crush artefacts in the specimen, the tissue injuries in the biopsy cavity cause obviously more bleedings with use of the ATEC® system.

However, comparing the Mammotome® 8-gauge system vs. ATEC® 9-gauge system the bleeding rates ($p = 0.135$) and the postinterventional hematoma rates ($p = 0.352$) did not differ significantly. Using the large 8- and 9-gauge VAB systems, bleeding and hematoma are obviously more influenced by the greater biopsy cavity than by the different techniques of the rotating cutting knifes. In contrast, using the small 11- and 12-gauge VAB systems, the subanalysis of the Mammotome® 11-gauge system vs. the ATEC® 12-gauge system revealed significantly less bleedings ($p = 0.015$) and less hematoma ($p = 0.001$) for the Mammotome® 11-gauge system. Again, we consider the correlation of tissue fragmentation of the specimen and tissue injuries in the biopsy cavity as cause for higher bleeding and hematoma rates with the ATEC® system. The ATEC® system's lavage function to flush the biopsy cavity with NaCl solution 0.9% does not seem to influence the bleeding and postinterventional hematoma rates as the rates were comparable for the ATEC® 9-gauge system and the Mammotome® 8-gauge system with no significant differences.

Significant bleeding occurred in only four cases (2.2%) necessitating abortion of the VAB. In one case (0.6%) VAB had to be stopped due to pain. The reported results in literature are comparable with up to 3.9% significant bleedings.

Using larger needle sizes, there was a trend for more periinterventional bleedings and postinterventional hematoma, with level of significance for the Mammotome® device, however not for the ATEC® device. For both tested systems, there was only a tendency concerning scar formation.

It is essential for proper reading of follow-up mammograms after VAB that the radiologist is aware of potential misinterpretation due to scar formation, especially in terms of former VAB with benign histologic findings. Supported by our results for increased scar formation with use of larger needle sizes, it is necessary to specify the direction of the biopsy approach in all reports of minimal-invasive percutaneous breast biopsies. This is to recognize corresponding findings in the target area of former biopsy, and, thus, to obviate misinterpretation and further diagnostic procedures.

A limitation of the study is that our results do not allow evaluation of late development of scar formation after 24 months or later, as only a limited number of the enrolled patients offer data of follow-up longer than twelve months. However, only two studies report [5,6] a decrease of density and scar formation in a few cases after 12–48 months, indicating stable or regressive findings for scar formation over time. On the other hand, scar formation might develop later than six month after VAB, so we cannot exclude false negative results of scar formation in our database due to the 6-month follow-up. It is known, that especially after surgical excision late scar formation may occur, correlating with long healing process and large tissue resection, hematoma and seroma. In our study, we observed no changes in scar formation for any case or

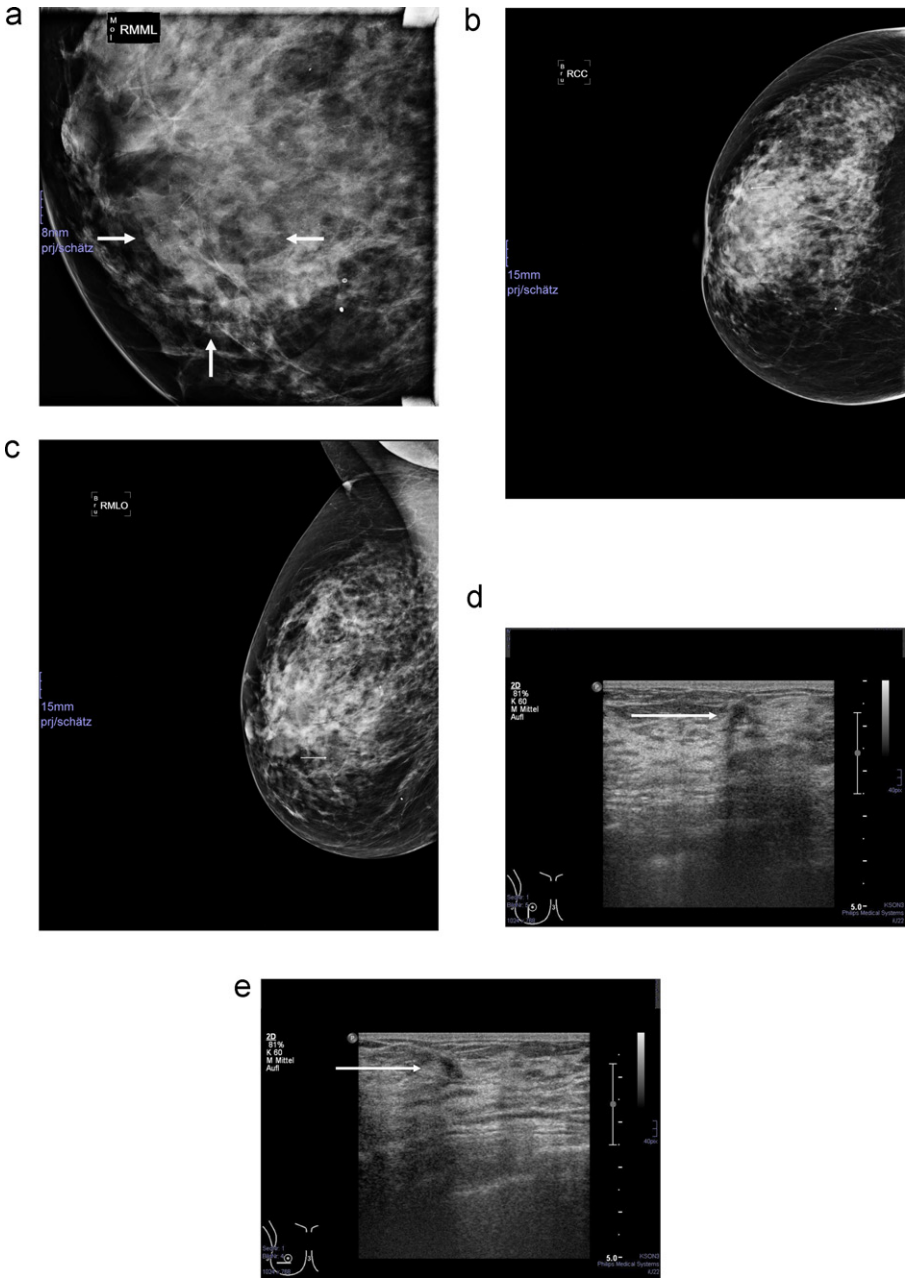

Fig. 4. (a) The magnification ml-view (a) of the digital mammogram pre biopsy shows an 20 mm × 20 mm area of suspicious microcalcifications (arrows, BI-RADS 4). Histology turned out as scleradenosis. (b) The cc-view (b) of the digital mammogram shows 2.5 cm lateral the nipple a moderate architectural distortion (arrow), parallel to the approach (cc) 6 month after VAB of the right breast with the 9g-ATEC®-VAB-system. (c) The mlo-view (c) of the digital mammogram shows 1.5 cm caudal the nipple (arrow) only a very small architectural distortion 6 month after VAB of the right breast with the 9 g- ATEC®-VAB-system. (d) Also in both planes of high resolution B-Mode-Ultrasound a small scar-formation (arrow) can be defined (d and e). (e) Also in both planes of high resolution B-Mode-Ultrasound a small scar-formation (arrow) can be defined (d and e).

late development for the cases with follow-up between 6 and 12 or 24 months.

In conclusion, the VAB techniques used guarantee a high technical success rate, permitting improvement in therapy planning and providing an alternative for open surgical biopsy. We believe that all examined VAB systems meet the requirements for daily practice.

References

[1] Schaefer F, Eden I, Schaefer PJ, Peter D, Jonat W, Heller M, Schreer I. Factors associated with one step surgery in case of non-palpable breast cancer. Eur J Radiol 2007;64(3):426–31.
[2] Ying-Hua Y, Liang C, Xi-Zi Y. Diagnostic value of vacuum-asisted breast biopsy for breast carcinoma: a meta-analysis and systematic review. Breast Cancer Res Treat 2010;120:469–79.
[3] Fahrbach K, Sledge I, Cella C. A comparison of the accuracy of two minimally invasive breast biopsy methods: a systematic literature review and meta-analysis. Arch Gynecol Obstet 2006;274:63–73.
[4] Peter D, Gruenhagen J, Wenke R, Schaefer FKW, Schreer I. False negative results after stereotactically guided vacuum biopsy. Eur Radiol 2007;18(1): 177–82.
[5] Lamm RL, Jackman RJ. Mammographic abnormalities caused by percutaneous stereotactic biopsy of histologically benign lesions evident on follow-up mammograms. Am J Roentgenol 2000;174:753–6.
[6] Yazici B, Sever AR, Mills P, Fish D, Jones SE, Jones PA. Scar formation after stereotactic vacuum-assisted core biopsy of benign breast lesions. Clin Radiol 2006;61:619–24.
[7] Brenner RJ, Pfaff JM. Mammographic changes after excisional breast biopsy for benign disease. Am J Roentgenol 1996;167:1047–52.
[8] Mendelson EB. Evaluation of the postoperative breast. Radiol Clin North Am 1992;30:107–38.
[9] O'Flynn EAM, Wilson ARM, Michell MJ. Image-guided breast biopsy: state-of-the-art. Clin Radiol 2010;65:259–70.

[10] Burbank F. Stereotactic breast biopsy: comparison of 14- and 11-gauge Mammotome probe performance and complication rate. Am Surg 1997;63:988–95.
[11] Parker SH, Klaus AJ. Performing breast biopsy with a directional, vacuum-assisted biopsy instrument. Radiographics 1997;17:1233–52.
[12] Zagouri F, Sergentanis T, Domeyer P, et al. Volume of blood suctioned during vacuum-assisted breast biopsy predicts later aemotoma formation. BMC Res Notes 2010;3:70.
[13] Kettritz U, Rotter K, Schreer I, Murauer M, Schulz-Wendtland D, Peter D, Heywang-Köbrunner SH. Stereotactic vacuum-assisted breast biopsy in 2874 patients: a multicenter study. Cancer 2004;100:245–51.
[14] Jackman RJ, Marzoni Jr FA, Nowels KW. Percutaneous removal of benign mammographic lesions: comparison of automated large-core and directional vacuum-assisted stereotactic biopsy techniques. Am J Roentgenol 1998;171:1325–30.
[15] Rotter K, Haentschel G, Koethe D, Goetz L, Bornhofen-Poeschke A, Lebrecht A, Kölbl H, Heywang-Köbrunner SH. Evaluation of mammographic and clinical follow-up after 755 stereotactic vacuum-assisted breast biopsies. Am J Surg 2003;186:134–42.